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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/448,356	11/23/1999	DAVID CARL BURDICK	20257/110665	4950
7590	07/26/2002			
MARK E WADDELL ESQ BRYAN CAVE LLP 245 PARK AVENUE NEW YORK, NY 101670034			EXAMINER QAZI, SABIHA NAIM	
		ART UNIT 1616	PAPER NUMBER	
DATE MAILED: 07/26/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/448,356	BURDICK ET AL.
	Examiner	Art Unit
	Sabiha Naim Qazi	1616

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 May 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) 9-23 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6, 8, 24 and 25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Prosecution Application

The request filed on 5/14/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/448,356 is acceptable and a CPA has been established. An action on the CPA follows.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Claims 1-6, 8-25 is pending, 1-6, 8, 24 and 25 are rejected, and others are withdrawn from consideration as non-elected invention. Restriction is made FINAL.

No claim is allowed.

All the rejections are withdrawn because claims are amended and arguments are found persuasive.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,3, 24 and 25 rejected under 35 U.S.C. 102(b) as being anticipated by

1. Benesova, V. See RN 81053-28-3 that is an ergost-5-en-3-ol, docosanoate.

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2. Lusby, William R. et al. see RN 94365 which is ergost. -5-en-3-ol, 9, 12, 15-octadecatrienoate (having three double bonds).

3. Austin et al. See RN 22554-56-9 which is stigmast-5-en-3-ol, docosanoate.

Amended claims contain a limitation of being the compounds liquid at temperatures from about -20C to about 20C. Since the property of being an oil or liquid at given temperature is inherent with the compound and is not critical for the invention. All the compounds cited above are anticipated by the prior art.

See Ex parte Novitski, 26 USPQ 2d 1389 (January 22, 1993) which is decision of USPTO Board of Appeals, holding to be inherent and not patentable, inoculating healthy plants with a known plant inoculant, employed in the prior art to protect them against phytopathogenic fungi. Novitski discovered that the known plant inoculants would also protect them against root dwelling plant pathogenic nematodes, a discovery neither known nor appreciated by the prior art. The step of inoculating plants with the same inoculants necessarily and inherently protects them against nematodes.

Claim Rejections - 35 USC § 112

Claim 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "comprising" cited in claim 8 is inclusive and fails to exclude unrecited steps. The use of the term comprising to introduce claimed structure means that the ingredients covered by these claims may involve more elements than those positively recited. *Ex parte Gottzein et al.*, 168 USPQ 176 (PTO Bd. App. 1969). Comprising

leaves the claim open for inclusion of unspecified ingredients even in major amounts.

Ex parte Davis et al., 80 USPQ 448 (PTO Bd. App. 1948).

Claim 24 is probably a duplicate of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as obvious over Mitchell (US Patent 4,588,717), Kamarei et al. (US Patent 4,879,312) and Miettinen et al. (WO 92/19640). See the entire documents especially lines 1-33, col. 7; col. 1-37, col. 8, equation 1 and examples in US '717; lines 39-59, col. 2 in US '312 and lines 22-30, page 9 and lines 20-24, page 10; lines 4-6, page 5; lines 8-37, page 6 in WO '640.

1. Determining the scope and contents of the prior art.

Prior art teaches a composition which embraces applicants claimed invention. Mitchell teaches vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigmasterol and taxasterol, in various combinations. Fatty acid have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups (lines 2-15, col. 6) and at least two double bonds such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters, (see lines 21-58, col. 3; lines 43-65, col. 5; equation 1 and lines 1-11 in col. 8). Furthermore, it teaches that the reaction between any given phytosterol and any given fatty acid is essentially the same,

and is characterized in equation 1 using sitosterol and linoleic acid as an exemplary fatty acid.

Miettinen et al. teaches a composition of b-sitostanol fatty acid ester mixture or fatty acid ester mixture. It teaches that physical properties of mixture can be modified easily by altering the fatty acid composition of the mixture. In addition to this, the fatty acid composition of the b-sitostanol fatty acid can also be selected so as to contain large amounts of monoenes and polyenes, whereby efficacy in lowering the cholesterol levels in serum are enhanced. See lines 22-30 on page 9. The reference also teaches fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol.

Kamarei et al. teach that a diet rich in omega-3-fatty acids has beneficial effects in humans, including a reduction in plasma cholesterol and triglyceride levels, improved fat tolerance, prolonged bleeding time reduce platelet counts and decreased platelet adhesiveness. The omega-3-fatty acids are obtained mainly from dietary seafood. It teach n-3 Poly unsaturated fatty acids (PUFA) participation and reasons why these materials may be involved in alleviating ischemic heart diseases. Furthermore, it also teaches that one of n-3 PUFA i.e. eicosapentaenoic acid (EPA) and DHA reduces triglyceride and very low-density lipoprotein (VLDL) serum levels and reduces whole blood viscosity. (See lines 39-59, col. 2; lines 13-54, col. 3; Table 1 and 2 in col. 4).

2. Ascertaining the differences between the prior art and the claims at issue.

Instant claim 8 is drawn to a composition comprising:

- (a) a phytosterol compound produced from a reaction of phytosterol with eicosapentaenoic acid or docosahexaenoic acid and

- (b) a second ester compound which is the product of an esterification reaction between a phytosterol and/or phytostanol and
- (i) a fatty acid having less than 18 or more than 22 carbon atoms and at least three carbon-carbon double bonds and/or
- (ii) a fatty acid having 18-22 carbon atoms and less than three double bonds.

Instant claims differ from the reference in claiming a composition containing combination of phytosterol ester compound produced by reaction of phytosterol and specific fatty acids eicosapentaenoic acid (EPA) (20-carbons) and or docosahexaenoic acid (DHA) (22-carbons), whereas prior art teaches compounds with fatty acids especially containing approximately 2-22 carbon atoms (lines 20-24, page 10). Instant claim is a selection of prior art teachings as EPA and DHA contain 20 and 22 carbons respectively which is taught by the prior art, see lines 20-25 on page 10 of WO '640 and US '717.

3. Resolving the level of ordinary skill in the pertinent art.

Therefore, it would be obvious to one skilled in the art at the time of invention to employ phytosterols composition in combination with omega-3-fatty acids and methods for lowering cholesterol and triglycerides in blood stream of a subject, because these agents are known individually for the treatment of the same disorders. See example 4 on page 11 of WO '640, where other oils such as sunflower, soybean olive and corn oil can also be used, which contain EPA and DHA. All the ingredients of the instant invention are taught by the prior art for the same use.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The combination of agents, each of which is known for the same purpose, is considered *prima facie* obvious. At least additive therapeutic results would be expected. See *In re Kerkhoven* 205 U.S. P.Q. 1069.

Motivation is to prepare additional beneficial composition of sterols with unsaturated fatty acids such as omega-3-fatty acids, EPA, DHA, useful for lowering the cholesterol and triglyceride levels, because this use has been taught by the prior art for the said compositions. Preparation of supplemental vitamins, margarine and mayonnaise is taught by the prior art cited above.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2. Claim(s) 1-6, 24 and 25 are rejected under 35 U.S.C. 103 as being unpatentable over combined teachings of Miettinen et al. (WO 92/19640) and Mitchell (US 4,588,717). Mitchell (US Patent 4,588,717) teaches vitamin supplements containing phytosterol esters such as fatty acid esters of sterol, stigmasterol and taxasterol, in various combinations, a composition of the phytosterols, such as sitosterol, stigmasterol, taraxasterol etc reacted with linoleic acid, (18-carbons, two double bonds), linolenic acid (18-carbons, 3-double bonds), arachidonic acid (20-carbons, two double bonds). Fatty acid have about 18-20 in addition to two carbon atoms of terminal carboxyl and methyl groups (lines 2-15, col. 6) and at least two double bonds

such as arachidonic acid, linoleic acid and linolenic acids are used to make phytosterol esters, (see lines 21-58, col. 3; lines 43-65, col. 5; equation 1 and lines 1-11 in col. 8). Furthermore, it teaches that the reaction between any given phytosterol and any given fatty acid is essentially the same, and is characterized in equation 1 using sitosterol and linoleic acid as an exemplary fatty acid.

Miettinen et al. teaches a composition of b-sitostanol fatty acid ester mixture or fatty acid ester mixture. It teaches that physical properties of mixture can modified easily by altering the fatty acid composition of the mixture. In addition to this, the fatty acid composition of the b-sitostanol fatty acid can also be selected so as to contain large amounts of monoenes and polyenes, whereby efficacy in lowering the cholesterol levels in serum are enhanced. See lines 22-30 on page 9. The reference also teaches fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol which is instantly claimed. See the entire documents especially lines 22-30, page 9 and lines 20-24, page 10; lines 4-6, page 5; lines 8-37; page 6 in WO '640.

Instant claims differ from the reference in claiming reaction of phytosterol with specific fatty acids i.e. docosahexaenoic acid and eicosahexaenoic acid where as prior art teaches reaction product of phytosterol with fatty acids especially containing approximately 2-22 carbon atoms. Instant claims are a selection of prior art teachings.

It would have been obvious to one skilled in the art to prepare additional beneficial composition by selecting any fatty acids for example, docosahexaenoic acid and eicosahexaenoic acid from fatty acid 2-22 carbon atoms taught by the prior art. There has been ample motivation provided by the prior art to prepare the instant

invention. Instant compositions would have been obvious at the time of invention. The subject as instantly claimed would have been obvious to one at the time of invention.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

July 25, 2002



SABIHA QAZI, PH.D
PRIMARY EXAMINER